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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Certifier A. Corbin

Food and Drug Administration

[Docket No. 02D–0028]

Medical Devices; Class II Special Controls Guidance Document: Cyclosporine and Tacrolimus Assays; Draft Guidance for Industry and FDA; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Class II Special Controls Guidance Document: Cyclosporine and Tacrolimus Assays; Draft Guidance for Industry and FDA." Elsewhere in this issue of the **Federal Register,** FDA is issuing a proposed rule to reclassify cyclosporine and tacrolimus assays from class III to class II when used as an aid in the management of transplant patients. If these devices are reclassified, this draft guidance will serve as the special control for the reclassified devices. This draft guidance is neither final nor in effect at this time.

DATES: Submit written or electronic comments concerning this guidance by [insert *date 60 days after date of publication in the* **Federal Register].**

ADDRESSES: Submit written requests for single copies on a 3.5" diskette of the draft guidance entitled "Class II Special Controls Guidance Document: Cyclosporine and Tacrolimus Assays; Draft Guidance for Industry and FDA" to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301-443-88 18. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance. Submit written comments concerning this draft guidance to the Dockets Management

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Branch (HFZ–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. Comments are to be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jean M. Cooper, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594-1243.

SUPPLEMENTARY INFORMATION:

I. Background

This draft guidance was developed as a special controls guidance to support the proposed reclassification of cyclosporine and tacrolimus assays from class III to class II. When final, this. guidance will replace the document "Guidance Criteria for Cyclosporine PMAs" dated January 24, 1992. That document was intended to cover the basic science, clinical experience, and issues identified through the review of premarket approval applications (PMAs) for cyclosporine. The agency has updated that guidance. The revised guidance has been retitled "Class II Special Controls Guidance Document: Cyclosporine and Tacrolimus Assays; Draft Guidance for Industry and FDA." On its own initiative, the agency has included tacrolimus assays in addition to cyclosporine assays in the revised guidance because the tacrolimus assay has the same intended use as an aid in the management of transplant patients. The agency believes it is taking a least burdensome approach by including tacrolimus assays in the revised guidance and will include tacrolimus assays in the proposed reclassification.

II. Significance of the Guidance

The draft guidance, when finalized, will represent the agency's current thinking on cyclosporine and tacrolimus assays. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute and regulations.

The agency has adopted good guidance practices (GGPs), and published the final rule, which set forth the agency's regulations for the development, issuance, and use of guidance documents (21 CFR 10.115). This draft guidance document is issued as a level 1 guidance in accordance with the GGP regulations.

III. Electronic Access

In order to receive "Class II Special Controls Guidance Document: Cyclosporine and Tacrolimus Assays; Draft Guidance for Industry and FDA" via your fax machine, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number 1380 followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes the civil money penalty guidance documents package, device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh. "Class II Special Controls Guidance Document: Cyclosporine and Tacrolimus Assays; Draft Guidance for Industry and FDA" will be available at http://www.fda.gov/cdrh/ode/guidance/1380.pdf.

IV. Comments

Interested persons may submit to Dockets Management Branch (address above) written or electronic comments regarding this draft guidance by *[insert date 60 days after date of publication*

in the **Federal Register].** Submit two copies of any comments, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 2/11/02

February 11, 2002.

Linda S. Kahan

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